EXHIBIT B

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April 16, 2019

VIA EMAIL
SAGoldberg@duanemorris.com
Seth A. Goldberg, Esq.
Duane Morris LLP
30 South 17th Street
Philadelphia, Pennsylvania 19103-4196

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Seth:

This letter is written to present narrowed core discovery requests in accordance with the Court's instructions during the April 10, 2019 status conference. This includes the categories of documents you have already agreed to produce, the ANDA files, Master Drug Files, and all communications to and from the FDA with regard to the contamination/impurities at issue in this litigation. To avoid miscommunication, we would appreciate it if you would define the scope and content of the ANDA files, the Master Drug Files, and confirm that the FDA communications will include communications regarding potential contamination or impurities prior to the July 2018 announcement of the recalls.

1. All communications with foreign regulatory authorities with regard to the contamination/impurities at issue in this litigation, including the EU, Canada, India, China, and Israel. (referenced by Judge Kugler during the first CMC).

2. The nature and extent of the contamination, including variations from lot to lot or by other demarcations, as applicable, to the extent known and easily produced.

3. How and when the contamination of the Valsartan occurred.

4. How and when each defendant discovered that the contamination of the Valsartan occurred, and the steps taken in response.

5. All results of testing for impurities of API and finished product going back to 2010.

6. Any changes to the manufacturing process, from 2010 to the present, including communications with regulatory agencies relative to the changes to the manufacturing process.

7. To the extent the manufacturing process was changed from 2010 to the present, all testing or quality assurance reviews, audits, or oversight, in connection with the change, and the results.

8. Quality assurance inspection reports or cGMP inspection/audit reports with regard to the manufacturing process.

9. Readily available documentation of the evaluation of the health risks posed by the contamination.

10. To the extent easily identifiable and retrievable, (1) the quantity of non-contaminated, and potentially contaminated Valsartan pills sold by any defendant in the United States, (2) the dosages of those pills, and (3) the prices charged.

11. The disposition or storage status of all potentially contaminated pills, including those that have and have not been tested.

Please advise as to which of these requests you agree to respond to, and which we need to meet and confer about, and please advise as to when during the next week we can do so.

Very truly yours,

ADAM M. SLATER

cc: Ruben Honik, Esq.
Daniel Nigh. Esq.
David J. Stanoch, Esq.
Conlee Whiteley, Esq.